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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,590	10/27/2000	Judith Fitzpatrick	018792/0177	3507

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WASHINGTON, DC 20007

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/697,590	<b>Applicant(s)</b> FITZPATRICK ET AL.	
	<b>Examiner</b> Sharon L. Turner	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 7-22, 24 and 26-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 23, 25 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-28-04 has been entered.
2. The amendment filed 11-26-03 has been entered into the record and has been fully considered.
3. Claims 1-54 are pending.
4. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
5. As a result of Applicants amendment, all rejections not reiterated herein have been withdrawn by the Examiner.

**Election/Restriction**

6. Applicant's election with traverse of Group I, claims 1-10 and 23-25 and 54 in part drawn to the extent of the peptide HARL, designated as SEQ ID NO:2, residues 292-295 in Paper No. 10 is acknowledged.

The traversal is on the ground(s) that the peptides are sufficiently related to at least claims 26-53 directed to various methods of using the peptides and that a thorough search would necessarily encompass a search for the methods of use and would not constitute a serious burden. Applicants argue that the search and

examination of overlapping sequences does not represent an undue burden.

This is not found persuasive because each of the inventions are patentably distinct as each delineates different sequence structure capable of different effects, functions and use. A search for one would not necessarily constitute a search for the other. Further it is noted that the election of peptide sequence as required in the restriction requirement is as an election of invention and not of species as indicated by applicant. A search of any particular sequence does not represent a search of any other and the claim structure does not evidence a proper genus. Rejoinder would only be reconsidered upon the indication of an allowable generic claim with common structure and function as required. The requirement is still deemed proper and is therefore made FINAL.

7. In the response of 1-28-04 claim 1 was amended so that it is no longer drawn to the HARL element. Thus, claims 1 and 2 are no longer directed to the elected invention. Claims 6, 23, 25 and 54 are drawn to the elected invention.

8. Claims 1-5, 7-22, 24 and 26-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

#### **Claim Objections**

9. Claims 23, 25 and 54 are objected to as being drawn in part to nonelected subject matter.

10. Claims 23, 25 and 54 are objected to as the article "an" prior to "NTP" should be

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"a".

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 6, 23, 25 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10146130. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application is similarly drawn to isolated neural thread protein (NTP) peptides. While the '130 claims are drawn to the peptides provided in a composition of matter claim, patenting of the claim may render obvious instant peptide comprising the same segment of neural thread protein as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

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13. Claims 6, 23, 25 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 6 is newly directed to "no more than 21 additional amino acids, wherein said additional amino acids correspond to amino acid residues that flank said HARL sequence in a neural thread protein (NTP)." Claim 23 is newly directed to "wherein (i) said peptide contains no more than 25 amino acids, (ii) any amino acids flanking said sequence correspond to amino acid residues that flank said sequence in a neural thread protein (NTP), and (iii) said peptide binds to an NTP." Claim 25 is newly directed to "but no more than 25 additional amino acids, (ii) said additional amino acids correspond to amino acid residues that flank said sequence in a neural thread protein (NTP), and (iii) said peptide binds to an NTP." Claim 54 is newly directed to language of "homologs thereof, wherein (i) said peptide contains no more than 25 amino acids, (ii) any amino acids flanking said sequence correspond to amino acid residues that flank said sequence in a neural thread protein (NTP), and (iii) said peptide binds to an NTP."

Applicants point to support for the new recitations within page 9, lines 7-8, and 14-16, page 11, lines 3-17 and original claims 1, 9 and 25. However, the specification and claims at such notations fails to provide adequate support of the recitations as now claimed. In particular, the combination of length limitations, flanking amino acids corresponding to NTP and functional activity of binding is not apparently supported as

now recited. Thus, the recitations constitute new matter absent evidence for support in the specification and claims as originally filed.

### **Claim Rejections - 35 USC § 102**

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 6, 23, 25 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Monte et al., US Patent 5,830,670 filed 5-30-1995 and issued 11-3-1998.

Monte et al., teach isolated neural thread protein comprising or having the HARL motif, see in particular SEQ ID NO:120. The peptide is flanked by portions of the neural thread protein sequence. While the claim stipulates the peptide to conform to particular length limitations (no more than 21 or 25), the full length peptide meets the claim limitations in that the peptide is claimed with "having" or "comprising" language. It is also clear that the art is properly applied as Applicants have made clear in the response to the previous 112, second paragraph rejection that the peptide can "contain additional non-amino acid elements or exist in a larger context." The full-length protein exists in a larger context. Moreover, Monte notes that neural thread protein aggregates and binds to itself, see in particular examples 2-3, 12 and 14-16, particularly in Alzheimer's and Down's syndrome plaques. Thus the full length peptide meets the claim limitations.

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The peptide is inherently a homolog and mimetic as it comprises the relevant residues as claimed. Thus the reference teachings anticipate the claimed invention.

### **Status of Claims**

16. No claims are allowed.

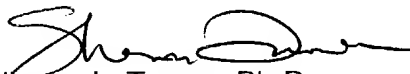
### **Conclusion**

17. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

  
Sharon L. Turner, Ph.D.  
May 28, 2004